

EXHIBIT # 7

AUG - 3 2006

510(k) Summary

In accordance with section 513(l) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

The Kendall Company
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: May 19, 2006

1. Contact Person

Michelle Kelley
Regulatory Affairs Associate
(508) 261-8530

2. Name of Medical Device

Classification Name: Syringe, Antistick

Common or Usual Name: Syringe with Sharps Injury Prevention Feature.

3. Identification of Legally Marketed Device

The proposed Kendall Monoject® Safety Syringe is substantially equivalent in intended use, design and function to the Kendall Monoject® Safety Syringe 510(k) No. K922522.

4. Device Description

The proposed device consists of a sterile syringe, labeled for either U-100 Insulin or Tuberculin, with a permanently attached single lumen needle, and an attached safety shield. The segmented safety shield is designed to be extended over the needle and locked. Activation is performed by a finger-tip or thumb operation or by pressing the shield. Once activated, the safety shield is securely and permanently locked.

5. Device Intended Use

The proposed device is primarily intended for delivery of U-100 Insulin or Tuberculin, as indicated. The safety shield is designed to protect against sharps injuries when activated.

6. Product Comparison

The proposed device has the same technological characteristics as the predicate devices. Each device consists of a sterile syringe, a permanently attached single lumen needle, with a manually operated safety feature.

7. Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2006

Ms. Michelle Kelley
Regulatory Affairs Associate
Tyco Healthcare
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K061492
Trade/Device Name: Kendall Monoject Magellan Insulin and Tuberculin
Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: May 19, 2006
Received: May 31, 2006

Dear Ms. Kelley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061492

Device Name: Kendall Monoject Magellan Insulin Safety Syringe

Indications For Use:

The device is intended for the delivery of U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rishi Chharia
(Signature)
Director of Anesthesiology, General Hospital,
FDA, Division of Anesthesia, Dental Devices
(Signature) K061492

Page 1 of 1

Indications for Use

510(k) Number (if known): K061492

Device Name: Kendall Monoject Magellan Tuberculin Safety Syringe

Indications For Use:

The device is intended for the delivery of Tuberculin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature] for *ADW* 8/3/2004

(Signature Sign-Off)

Division of Anesthesiology, General Hospital,
Division Control, Dental Devices

510(k) Number: K061492

Page 1 of 1